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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/471,669	12/24/99	ANDERSON J	00228-US-NEW

EXAMINER	
CROUCH, D.	
ART UNIT	**PAPER NUMBER**
1632	9

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DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/471,669	ANDERSON ET AL.	
	Examiner	Art Unit	
	Deborah Crouch	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-113* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, drawn to β-secretase, classified in class 435, subclass 195.

II. Claims 37-46, drawn to composition comprising a β-secretase and a β-secretase substrate or inhibitor, classified in class 435, subclass 195.

III. Claim 47, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claim 48-69, drawn to a nucleic acid encoding β-secretase, expression vectors, cells and methods to make, classified in class 536, subclass 23.2.

V. Claims 70-74,78 and 79, drawn to methods of screening for compounds that inhibit Aβ production using a transfected cell expressing β-secretase, classified in class 435, subclass 29.

VI. Claims 70, 75-79 and 100-102, drawn to methods of screening for compounds that inhibit Aβ production using a transgenic animal, classified in class 800, subclass 3.

VII. Claims 80-85, drawn to method of screening for compounds that inhibit Aβ production by measuring binding of β-secretase with a β-secretase inhibitor, classified in class 435, subclass 4.

VIII. Claims 86-90, drawn to a β-secretase inhibitor, can not be classified.

IX. Claims 91-95, drawn to a kit, classified in class 435, subclass 4.

X. Claims 96-99, drawn to a knock out mouse, classified in class 800, subclass 18.

XI. Claims 103-107, drawn to a method to treat comprising administering a compound that inhibits β-secretase and a drug that inhibits β-secretase activity, classified in class 424, subclass 570.

XII. Claims 108-110, drawn to method of diagnosing AD comprising measuring β-secretase activity in a cell sample, classified in class 435, subclass 29.

XIII. Claims 111-113, drawn to method of purifying β-secretase by affinity matrix with inhibitor, classified in class 530, subclass 413.

The inventions are distinct, each from the other because:

Inventions I and II are distinct because they are of separate uses. The β-secretase of invention I can be use to produce antibodies. The composition of invention II can be used in an assay to determine inhibitors of the inhibitor.

Inventions I and III are distinct because they are of separate uses. The β-secretase of invention I can be use to produce antibodies. The antibody of invention III can be used in purification procedures.

Inventions I and IV are distinct because they are of separate uses. The β-secretase of invention I can be used to produce antibodies. The DNA sequence of invention IV can be used for the recombinant production of β-secretase.

Inventions I and V-VII are mutually exclusive and independent. The β-secretase of invention I is not needed for the method of screening of as in any of inventions V-VII, and vice versa.

Inventions I and VIII are distinct because they are of separate uses. The β-secretase of invention I can be used to produce antibodies. The β-secretase inhibitor of invention VIII can be used to inhibit β-secretase activity.

Inventions I and IX are distinct because they are of separate uses. The β-secretase of invention I can be used to produce antibodies. The kit of invention IX can be used to cleave a β-secretase substrate and detect the cleavage products.

Inventions I and X are distinct because they are of separate uses. The β-secretase of invention I can be used to produce antibodies. The knockout animal of invention X can be used to observe the effects of a null mutation on the animal's physiology.

Inventions I and XI are mutually exclusive and independent. The β-secretase of invention I is not needed for the method of treatment of invention XI, and vice versa.

Inventions I and XII are mutually exclusive and independent. The β-secretase of invention I is not needed for the method of diagnosis invention XII, and vice versa.

Inventions I and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case β-secretase can be purified by immuno-affinity chromatography.

Inventions II and III are distinct because they are of separate uses. Invention I is to a composition comprising β-secretase and a substrate or inhibitor. Invention III is to an antibody.

The composition of invention II can be used in as assay to determine the affect of compounds on β-secretase activity in the presence of a substrate or inhibitor. The antibody of invention III can be used in immuno-purification procedures.

Inventions II and IV are distinct because they are of separate uses. Invention I is to a composition comprising β-secretase and a substrate or inhibitor. Invention IV is to a DNA sequence encoding β-secretase. The composition of invention II can be used in as assay to determine the affect of compounds on β-secretase activity in the presence of a substrate or inhibitor. The DNA sequence of invention IV can be to produce β-secretase in transformed cells.

Inventions II and V-VII are mutually exclusive and independent. The composition of invention II is not needed for the assays of Inventions V-VII, and vice-versa.

Inventions II and VIII are distinct because they are of separate uses. Invention I is to a composition comprising β-secretase and a substrate or inhibitor. Invention VIII is to a β-secretase inhibitor. The composition of invention II can be used in as assay to determine the affect of compounds on β-secretase activity in the presence of a substrate or inhibitor. The inhibitor of invention VIII can be used to regulate β-secretase activity.

Inventions II and IX are distinct because they are of separate uses. Invention I is to a composition comprising β-secretase and a substrate or inhibitor. Invention IX is to a kit. The composition of invention II can be used in as assay to determine the affect of compounds on β-secretase activity in the presence of a substrate or inhibitor. The kit of invention IX can be used to measure rates of β-secretase activity.

Inventions II and X are distinct because they are of separate uses. Invention I is to a composition comprising β-secretase and a substrate or inhibitor. Invention X is to a knockout mouse. The composition of invention II can be used in as assay to determine the affect of compounds on β-secretase activity in the presence of a substrate or inhibitor. The mouse of invention X can be used to observe the effect of a β-secretase null mutation on the mouse's physiology.

Inventions II and XI are mutually exclusive and independent. The composition of invention II is not needed for the method of treatment of Invention XI , and vice-versa.

Inventions II and XII are mutually exclusive and independent. The composition of invention II is not needed for the method of diagnosis of Invention XII, and vice-versa.

Inventions II and XIII are mutually exclusive and independent. The composition of invention II is not needed for the method of purification of Invention XIII, and vice-versa.

Inventions III and IV are distinct as they are of separate uses. The antibody of Invention III can be used in immuno-affinity purification procedures. The DNA sequence of invention IV can be used to produce recombinant β-secretase.

Invention III and V-VII are mutually exclusive and independent. The antibody of invention III is not needed for any of the assays in inventions V-VII, and vice versa.

Inventions III and VIII are distinct as they are of separate uses. The antibody of Invention III can be used in immuno-affinity purification procedures. The β-secretase inhibitor of invention VIII can be used to inhibit β-secretase activity.

Inventions III and IX are distinct as they are of separate uses. The antibody of Invention III can be used in immuno-affinity purification procedures. The kit of invention IX can be used to determine the rates of β-secretase activity.

Inventions III and X are distinct as they are of separate uses. The antibody of Invention III can be used in immuno-affinity purification procedures. The mouse of invention X can be used observe the effect of a null β-secretase mutation on the animal's physiology.

Inventions III and XI are mutually exclusive and independent. The antibody of invention III is not needed for the method of treatment of invention XI, and vice versa.

Inventions III and XII are mutually exclusive and independent. The antibody of invention III is not needed for the method of diagnosis of invention XII, and vice versa.

Inventions III and XIII are mutually exclusive and independent. The antibody of invention III is not needed for the method of purification of invention XIII, and vice versa.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transfected cells of invention IV can be used to produce recombinant β-secretase..

Inventions IV and VI-VII are mutually exclusive and independent. The DNA sequence of invention IV is not required for either the assay of inventions VI or VII, and vice versa.

Inventions IV and VIII are mutually exclusive and independent. The DNA sequence of invention IV is not required for the β-secretase inhibitor of invention VIII.

Inventions IV and IX are mutually exclusive and independent. The DNA sequence of invention IV is not required for the kit of invention IX.

Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA sequence of invention IV can be used to produce recombinant β-secretase.

Inventions IV and XI are mutually exclusive and independent. The DNA sequence of invention IV is not required for the method of treatment using a β-secretase inhibitor of invention XI.

Inventions IV and XII are mutually exclusive and independent. The DNA sequence of invention IV is not required for the method of diagnosing of invention XII.

Inventions IV and XIII are mutually exclusive and independent. The DNA sequence of invention IV is not required for the method of purification of invention XIII.

Inventions V and VI are mutually exclusive and independent methods of screening. The method of invention V uses transfected cells as the assay medium. The method of invention VI uses a transgenic animal as the screening medium.

Inventions V and VII are mutually exclusive and independent methods of screening. The method of invention V uses transfected cells as the assay medium. The method of invention VII uses an in vitro medium to determine inhibitor binding.

Inventions V and VIII are mutually exclusive and independent. The method of assay of invention V does not require the β-secretase inhibitor of invention VIII, and vice versa.

Inventions V and IX are mutually exclusive and independent. The method of assay of invention V does not require the kit of invention IX, and vice versa.

Inventions V and X are mutually exclusive and independent. The method of assay of invention V does not require the knockout animal of invention X, and vice versa.

Inventions V and XI are mutually exclusive and independent. The method of assay of invention V does not require the method of treatment of invention XI, and vice versa.

Inventions V and XII are mutually exclusive and independent. The method of assay of invention V, using transfected cells requires materially different and separate protocols from those of a method of diagnosis of invention XII, using transfected cells. In addition, neither method is needed for the other method.

Inventions V and XIII are mutually exclusive and independent. The method of assay of invention V does not require the method of purification of invention XIII, and vice versa.

Inventions VI and VII are mutually exclusive and independent. The method of assay of invention VI is an in vivo assay using an animal as the assay medium. The protocols for an animal

assay are materially different and separate from those required for invention VII, where the screening is performed in an in vitro medium.

Inventions VII and VIII are mutually exclusive and independent. The method of screening of invention VII is not required for the β-secretase inhibitor of invention VIII, and vice versa.

Inventions VII and IX are mutually exclusive and independent. The method of screening of invention VII is not required for the kit of invention IX, and vice versa.

Inventions VII and X are mutually exclusive and independent. The method of screening of invention VII is not required for the knock out mouse of invention X, and vice versa.

Inventions VII and XI are mutually exclusive and independent. The method of screening of invention VII is not required for the method of purification of invention XI.

Inventions VIII and IX are mutually exclusive and independent. The β-secretase inhibitor of invention VIII is not needed for the kit of invention IX, and vice versa.

Inventions VIII and X are mutually exclusive and independent. The β-secretase inhibitor of invention VIII is not needed for the knockout animal of invention X, and vice versa.

Inventions VIII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the β-secretase inhibitor can be used to prepare a composition of β-secretase and an inhibitor of β-secretase.

Inventions VIII and XII are mutually exclusive and independent. The β-secretase inhibitor of invention VIII is not needed for the method of diagnosis of invention XII, and vice versa.

Inventions VIII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the β-secretase inhibitor can be used to make a composition of β-secretase and a β-secretase inhibitor.

Inventions IX and X are mutually exclusive and independent. The kit of invention IX is not needed for the knock out animal of invention X, and vice versa.

Inventions IX and XI are mutually exclusive and independent. The kit of invention IX is not needed for the method of treatment of invention XI, and vice versa.

Inventions IX and XII are mutually exclusive and independent. The kit of invention IX is not needed for the method of diagnosis of invention XII, and vice versa.

Inventions IX and XIII are mutually exclusive and independent. The kit of invention IX is not needed for the method of purification of invention XIII, and vice versa.

Inventions X and XI are mutually exclusive and independent. The knockout animal of invention X is not needed for the method of treatment of invention XI.

Inventions X and XII are mutually exclusive and independent. The knockout animal of invention X is not needed for the method of diagnosis of invention XII.

Inventions X and XIII are mutually exclusive and independent. The knockout animal of invention X is not needed for the method of purification of invention XIII.

Inventions XI and XII are mutually exclusive and independent. The methods of treatment of invention XI required materially different and separate protocols from those required for the method of diagnosis of invention XII. In addition, neither method is required for the implementation of the other method.

Inventions XI and XIII are mutually exclusive and independent. The methods of treatment of invention XI required materially different and separate protocols from those required for the method of purification of invention XIII. In addition, neither method is required for the implementation of the other method.

Inventions XII and XIII are mutually exclusive and independent. The methods of diagnosis of invention XII requires materially different and separate protocols from the method of purification of invention XIII. In addition, neither method is required for the implementation of the other method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Karen Hauda, whose telephone number is (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

The fax number is (703) 308-4242.

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Dr. D. Crouch
February 12, 2001